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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/330,903	06/11/1999	IGOR GONDA	6513/061US1	9995

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BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD RD
SUITE 200
MENLO PARK, CA 94025

EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/16/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/330,903Applicant(s)
GondaExaminer
Richard SchnizerArt Unit
1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Sep 23, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s):

None.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
- See attached.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None

Claim(s) objected to: _____

Claim(s) rejected: 57-64 and 66-71

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

10. ☐ Other: _____

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ADVISORY ACTION

Applicant sets forth three basic concepts in the instant invention and argues at page 6 of the response that the cited art does not teach any of the basic concepts alone or in combination.

The three concepts are:

- (1) a particle comprising a polynucleotide and a condensing agent;
- (2) adjustment of aerosol particle size to target specific regions of lung; and
- (3) controlling the volume of aerosol inhaled

Applicant's argument is unpersuasive. Debs teaches concept (1). See claim 3 at column 15. Each of Debs, Schuster, and Radhakrishnan teach concept (2). See Debs at column 12, lines 51-61, and claim 1, 14, 15, and 16. See Schuster at column 20, lines 30-50. See Radhakrishnan, Fig. 3. Schuster teaches concept 3 at, for example, claim 6 which bridges columns 38 and 39.

In the first full paragraph of page 6, Applicant argues that the cited art does not teach adjusting the size of the aerosol particles while also adjusting the inhaled volume of aerosol. This is incorrect. As noted above, Schuster teaches this concept at claim 6 which requires control over inhalation volume, and passage of particles through a membrane that adjusts the size of the particles. Applicant also argues that the cited art does not teach these concepts in combination with the use of a condensing agent. It is true that no single reference teaches this combination. However, the rejection is made under 35 USC 103, not 102, so the combination of references is allowed.

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Applicant argues in the second full paragraph of page 6 that the combination of Debs and Schuster is unrealistic because Debs does not teach toward adjustment of inhaled volume in order to target areas of the lung. This is unpersuasive because Debs is not relied upon to teach adjustment of inhaled volume, Schuster teaches this. Applicant has not addressed the Office's stated of motivation to combine the references. One would have been motivated to use the device and method of Schuster to deliver the particles of Debs because while both Debs and Schuster recognize that the control of particle size allows one to target specific regions of the lung, Debs teaches that this can be accomplished by using nebulizers of different characteristics, whereas Schuster teaches a single device that allows selection of particle size simply by changing the membranes. Clearly one of ordinary skill in the art, aware of both teachings, would have been motivated to combine them. The remainder of Applicant's arguments are directed to the failure of the remaining references to make up for the supposed deficiencies in Debs and Schuster. These arguments are unpersuasive because, as shown above, Debs and Schuster are not deficient references.

For these reasons the rejections are maintained.



**JAMES KETTER
PRIMARY EXAMINER**